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SCULLY, SCOTT, MURPHY & PRESSER
200 GARDEN CITY PLAZA
GARDEN CITY, NY 11530-3391

EXAMINER	
HOFFER, F	
ART UNIT	**PAPER NUMBER**
182	2

DATE MAILED: 04/12/88

This is a communication from the examiner in charge of your application.

COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), _____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☒ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice re Patent Drawing, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449
4. ☐ Notice of informal Patent Application, Form PTO-152
5. ☐ Information on How to Effect Drawing Changes, PTO-1474
6. ☐ _____

Part II SUMMARY OF ACTION

1. ☒ Claims 1-10 are pending in the application.

   Of the above, claims _____ are withdrawn from consideration.

2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 1-10 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings which are acceptable for examination purposes until such time as allowable subject matter is indicated.
8. ☐ Allowable subject matter having been indicated, formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. These drawings are ☐ acceptable; ☐ not acceptable (see explanation).
10. ☐ The ☐ proposed drawing correction and/or the ☐ proposed additional or substitute sheet(s) of drawings, filed on _____. has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved. ☐ disapproved (see explanation). However, the Patent and Trademark Office no longer makes drawing changes. It is now applicant's responsibility to ensure that the drawings are corrected. Corrections MUST be effected in accordance with the instructions set forth on the attached letter "INFORMATION ON HOW TO EFFECT DRAWING CHANGES", PTO-1474.
12. ☐ Acknowledgment is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

1. The Abstract of the Disclosure is objected to because if fails to fully comply with the requirements under 37 CFR 1.72(b). The abstract should be included under the heading --Abstract of the Disclosure-- and not merely "Abstract". Correction is required. See MPEP 608.01(b).

2. The disclosure is objected to because of the following informalities:

In the specification on page 20, line 6, it is uncertain if the author "Mulskin" is intended or if --Milstein-- is intended.

Appropriate correction of the disclosure is required.

3. Claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, as the disclosure is enabling only for claims limited in accordance with the specification. The broad term "antigen" is considered to be enabled by an antigen of ovarian cancer as set forth in the specification. The antigen with a 40 kilodalton molecular weight, therefore, the claims lack enablement in the specification. See MPEP 706.03(n) and 706.03(z).

is only enabled for the specific type of antigen recited therein and not enabled for any antigen

4. Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recital of "CA125" renders claim 1 (and all other instances) vague and indefinite as to the intended meaning. Is the CA125 antigen present only in ovarian cancer? The recitation of "time sufficient" renders claim 6 vague and indefinite as to the intended meaning. What do Applicants consider a sufficient time for the formation of a binary complex?

5. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 1 and 2 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Since the claims do not specifically recite "an isolated substantially purified subunit of CA125 antigen" they read on an antigen that exists in its native state, in vivo and are thus non-statutory.

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless-

8. (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

10. Claims 1-4 are rejected under 35 U.S.C. 102 (b) as anticipated by or, in the alternative, under 35 U.S.C. 103 as obvious over Masuno et al and Bast et al.

Masuno et al discloses a monoclonal antibody, OC 125, specific to disinct determinants on the surface of human ovarian cancer cells. Bast et al disclose monoclonal antibody, OC125, which recognizes the antigen CA125 which is the same antigen of the present invention. It is noted that Bast et al does not disclose a particular submit of this antigen. The specific determinants and antibody of Masuno et al inherently have the same characteristics as required by the claims. Since

the antigens are identical they would inherently posses the same specific cell-surface determinants or subunits. A difference in molecular weight could result from a difference in purity and/or a difference in molecular weight determination. In the event of unexpected results it would have been well within the purview of the skilled artisan through limited routine experimentation to detect the claimed subunit with highly conventional techniques.

11. Claims 5-10 are rejected under 35 U.S.C. 103 as being unpatentable over Masuno et al and Bast et al in view of Pestka or the WO Patent.

Masuno et al and Bast et al disclose as set forth supra. Pestka and the WO Patent disclose a two-site or sandwich assay employing polyclonal and mononclonal antibodies. A two-site assay is used to detect two distinct epitopes or determinants at two different sites on an antigen.

When detecting for the specific determinants of the CA125 antigen with the monoclonal antibodies of Masuno et al and Bast et al it would have been obvious to one of ordinary skill in the art to use the two-site or sandwich assay of Pestka or the WO Patent for the advantages associated with such assay methods. Also, the formation of a kit would have obvious since such kits are highly conventional.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Mattes et al disclose diagnosis and therapy for cancer patients employing monoclonal antibodies to several cell antigens of human ovarian, cervical and endemetrial carcinomas.

Knauf discloses a monoclonal antibody to a specific antigen derived from human ovarian carcinomas. Also disclosed is the use of this antibody in a radioimmunoassay for the detection of ovarian carcinomas.

The prior art reference cited by applicant on page 4 of the specification (Knaaf and Urback, AM. J. Obstet. Gynecol. 138: 1222, 1980) is not readily available to the Examiner. Applicants assistance is providing a copy to complete the record would be appreciated.

Any inquiry concerning this communication should be directed to Florina B. Hoffer at telephone number 703-557-0664.

FBH
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4/3/88

Robert J. Warden

ROBERT J. WARDEN
SUPERVISORY PATENT EXAMINER
ART UNIT 128